

# **EXHIBIT 9**

**ORIGINAL**

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**FILED**

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 RICHARD W. WIEKING  
 CLERK  
 U.S. DISTRICT COURT  
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16 X

8 IN THE UNITED STATES DISTRICT COURT  
 9 FOR THE NORTHERN DISTRICT OF CALIFORNIA  
 10

11 MILES INC.,	)	CIVIL ACTION NO.
	)	C 92 1975 VRW
12 Plaintiff,	)	
	)	
13 v.	)	
	)	
14 GREEN CROSS CORPORATION, a	)	
15 Japanese Corporation, and ALPHA	)	SCHEDULING CONFERENCE
16 THERAPEUTIC CORP., a California	)	<u>STATEMENT OF MILES INC.</u>
17 corporation,	)	
	)	
Defendants.	)	

18 This is a patent infringement action involving the  
 19 pharmaceutical immune serum globulin, which helps the human immune  
 20 system fight off certain infectious diseases (e.g., hepatitis).  
 21 Before the patented work by Plaintiff Miles Inc. ("Miles"), immune  
 22 serum globulin was sold in powdered form and had to be reconstituted  
 23 with water before use. There was a need and desire for a liquid  
 24 immune serum globulin; however, early liquid forms of immune serum  
 25 globulin were unstable and not suitable for intravenous injection.  
 26 Mr. Robert Tenold of Cutter Laboratories, a division of Miles, found  
 27 that the combination of low (acidic) pH and low buffer (salt) content  
 28 resulted in a stable, liquid product that could be intravenously  
 injected despite its relatively strong acidic nature. Mr. Tenold's  
 immune system globulin invention and the process of making it are  
 disclosed and claimed in the two patents-in-suit, U.S. Patent Nos.  
 4,396,608 ("'608 patent") and 4,499,073 ("'073 patent").

1           The parties attempted to file a joint statement; however,  
2 they were unable to present their respective positions within the  
page limitation and to agree on the content of the statement.

3 Miles respectfully submits its scheduling conference statement  
4 pursuant to the Order Setting Scheduling Conference.

5 I. Jurisdiction and Venue

6 Miles alleges that Defendants Alpha and Green Cross have  
7 been and are still infringing the '608 and '073 patents by making,  
8 using, and selling and inducing the manufacture of a solution of  
human intravenous immunoglobulin under the trademark Venoglobulin-S.  
9 This Court has subject matter jurisdiction of this action pursuant to  
Title 35 and 28 U.S.C. § 1338(a). Green Cross has acknowledged  
10 receipt of a Japanese translation of the Amended Complaint and  
Summons. However, Green Cross, a Japanese corporation, contends that  
11 it is not subject to the Court's in personam jurisdiction as it does  
12 not have sufficient contacts with the United States. Miles believes  
13 that Green Cross is subject to this Court's personal jurisdiction  
14 since Green Cross Corporation has a place of business in New York  
City and is an alter ego of defendant Alpha. The parties agree that  
15 venue is proper in the Northern District of California as to  
16 defendant Alpha pursuant to 28 U.S.C. § 1391(c) and 28 U.S.C. §  
17 1400(b).

18 II. Pivotal Issues

19 The central issue is whether Defendants' product infringes  
Miles' patents. One limitation in the claims of the patents is a pH  
20 range of "about 3.5 - 5.0." An analytical report from Miles shows  
that Defendants' product has a pH of 5.3 in a solution advertised as  
21 5%. Miles' position is that a pH of 5.3 is literally encompassed by  
the term "about" which precedes the claimed range of 3.5 - 5.0. S.C.  
22 Johnson & Son v. Carter-Wallace, Inc., 614 F. Supp. 1278, 1307-08,  
23 aff'd in part, 781 F.2d 198 (Fed. Cir. 1986); Flow-Rite of Tennessee  
24 v. Sears, Roebuck & Co., Inc., 20 U.S.P.Q.2d 1361 (N.D. Ill. 1991).  
25 Miles' analytical reports also show Defendants' product to have a pH  
26 of 5.5 in a 1% saline (sodium chloride salt) solution; however, this  
data is not relevant to the patent claims, which call for a pH  
27 measurement of a 5% solution of reduced ionic strength (reduced  
28 salt).

1 Although Miles contends that the literal infringement issue  
2 is dispositive, in the alternative, Miles asserts that the  
3 Defendants' product infringes under the doctrine of equivalents. A  
4 pH of 5.3 has the same function, performs in the same way, and  
5 produces the same result, namely, product stability, to fully meet  
the three legal elements necessary for a finding of equivalency.

#### 6 III. Attorney Fees, Costs and Interest

7 Miles believes that Defendants knew of its patents and  
8 attempted to avoid infringement by adjusting their pH just outside  
9 the pH range claimed in the patents. Former employees of Miles, who  
10 are employed by defendant Alpha, may have assisted in the development  
11 of Defendants' product. The willful and deliberate nature of the  
12 Defendants' infringement of Miles' patents makes this case  
13 exceptional within the meaning of 35 U.S.C. § 285, and Miles is  
14 therefore entitled to recover from both Defendants its costs of this  
15 suit, including reasonable attorney fees. Attorneys fees will be  
16 calculated on an hourly basis, based upon the daily time records of  
the attorneys. Costs will be determined based upon the monthly bills  
sent to the clients. Counsel for Miles has advised Miles that it  
will incur significant fees, costs, and interest, if this matter goes  
to trial.

#### 17 IV. Damage Claims

18 Miles will seek lost profits, or in the alternative,  
19 reasonable royalties. As there are only two companies in the market,  
20 Miles' lost profits will be equal to Alpha's sales multiplied by  
21 Miles' gross profit margin. In the alternative, Miles will seek  
damages equal to at least a royalty of 25%, which is reasonable in  
this industry.

#### 22 V. Settlement or Other Disposition

23 The principals have met since the complaint was filed, but  
24 did not engage in settlement discussions. Miles' position is that  
25 the Defendants are infringing its patents, and Miles wants them to  
26 stop. The parties are only able to agree that they are very far  
apart and that the prospects of settlement are poor.

#### 27 VI. Disclosure and Discovery

28 It is Miles' position that formal discovery cannot commence  
until after the September 4, 1992 Scheduling Conference. The Court's

1 Order Setting Scheduling Conference provides that the parties are  
2 required to make basic fact disclosure before engaging in formal  
3 discovery. Miles has done so by (1) giving Defendants copies of its  
4 analytical reports showing infringement; (2) giving Defendants a  
5 claims chart with Miles' contentions of how each element of the  
6 infringed claims is met by the accused product; and (3) a list of  
7 Miles employee names and addresses who have factual information  
8 pertinent to Miles' claims. Additional materials to be produced  
9 shortly are being gathered.

10 Miles' goal in the first round of discovery is to  
11 identify the people who developed Defendants' product and to fully  
12 determine the precise nature of the product and its method of  
13 production. Miles' first round of discovery will include requests  
14 for admissions, interrogatories, document requests, and depositions.  
15 Depositions will include: (1) the Alpha scientists who developed its  
16 product; (2) Alpha sales people; and (3) the ex-Miles employees, who  
17 are now employed by Alpha. Miles will also take the Rule 30(b)(6)  
18 deposition of Green Cross by telephone in Japan in order to oppose  
19 Green Cross's challenge to the personal jurisdiction of the Court.  
20 An additional deposition of Green Cross personnel in the United  
21 States may be needed. Miles' damage discovery will include Alpha's  
22 sales and profit margins, which are relevant to lost profits. Miles  
23 will also engage in expert discovery.

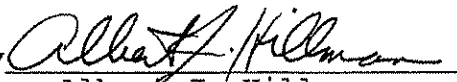
24 VII. Motions

25 Miles will file a partial summary judgment motion of  
26 infringement after the first round of discovery is completed.

27 The parties agree that it is in the interests of both  
28 parties and will conserve judicial resources to stay discovery on the  
damages issue and bifurcate the damages issue for a separate trial.  
The parties will file a joint motion with a proposed order for the  
Court's consideration.

Dated: August 25, 1992

Respectfully submitted,  
TOWNSEND AND TOWNSEND

By   
Albert J. Hillman  
Attorneys for Plaintiff  
MILES INC.

PROOF OF SERVICE BY COURIER AND REGULAR MAIL

I am a citizen of the United States and am employed in the City and County of San Francisco, State of California; am over the age of eighteen years; and am not a party to the above-entitled case. My business address is One Market Plaza, Steuart Street Tower, 20th Floor, San Francisco, California 94105.

On August 25, 1992, I served the attached SCHEDULING CONFERENCE STATEMENT on the parties in said action, by depositing a true copy thereof in the United States First-Class mail at San Francisco, California, enclosed in a sealed envelope, with the postage thereon fully prepaid, addressed as follows:

Howard L. Bernstein  
SUGHRUE, MION, ZINN,  
MACPEAK & SEAS  
Suite 800  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3202

and by having the same hand-delivered to:

Robert B. Pringle  
THELEN MARRIN JOHNSON & BRIDGES  
Suite 2200  
Two Embarcadero Center  
San Francisco, CA 94111-3995

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 25, 1992 at San Francisco, California.

Julie Taylor Clough  
Julie Taylor Clough